



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/538,964

06/14/2005

Doug Sweet

09138.0069

5627

63432 7590 06/24/2009
DAKO/FINNEGAN, HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

HENKEL, DANIELLE B

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

06/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/538,964 | Applicant(s) SWEET ET AL. | |
| | Examiner DANIELLE HENKEL | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-23, 25-30 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21-23, 25-30, 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed March 2, 2009 has been entered and fully considered.
2. The rejection of claim 17 under 35 U.S.C. 112 2nd paragraph is withdrawn in light of amendments.
3. Claims 1-19, 21-23, 25-30, and 32-36 are pending, of which 35-36 are new.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 3-5 all recite the limitation "said sample". There is insufficient antecedent basis for this limitation in the claim as the independent claim 1 has been amended to recite "at least one slide".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 8, 10-13, 16, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by TSEUNG (US 5439649).

Art Unit: 1797

a. With respect to claim 1, TSEUNG teaches an automatic staining apparatus comprising at least one removable reagent container positioned within a reagent section (Column 5, lines 3-5); at least one slide (Column 3, lines 65-67); a robotic element adapted to affect said reagent container and said slide (Column 4, lines 10-14); a control element to which said robotic element is responsive (Column 5, lines 7-13); an image capture 2D optical sensor configured to two dimensionally image at least one element in said automatic staining apparatus (Column 16, lines 42-51); wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51).

b. With respect to claim 8, TSEUNG teaches an automatic staining apparatus comprising at least one reagent container (Column 5, lines 3-5), at least one sample the sample being placed on a slide (Column 3, lines 65-67); a robotic element adapted to affect said reagent container and said sample (Column 4, lines 10-14); a control element to which said robotic element is responsive (Column 5, lines 7-13); an optical sensor adapted to locate pre-selected reference features for self-calibration of the robotic element (Column 16, lines 42-51); wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51).

Art Unit: 1797

- c. With respect to claim 10, TSEUNG teaches an automatic staining apparatus comprising at least one reagent container (Column 5, lines 3-5), at least one sample the sample being placed on a slide (Column 3, lines 65-67); a robotic element adapted to affect said reagent container and said sample (Column 4, lines 10-14); a control element to which said robotic element is responsive (Column 5, lines 7-13); an image capture 2D optical sensor configured to two dimensionally image at least one element in said automatic staining apparatus (Column 16, lines 42-51) wherein said at least one element comprises an optical identification element having reiterated information (Column 16, lines 42-47); wherein the control element monitors insertion or removal of the at least one removable reagent container and the at least one slide during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51).
- d. With respect to claims 11-13 and 16, the slide identification information (optical identification) in the form of a barcodes as taught by TSEUNG are by definition multiple iterations of lines in patterns which may repeat (redundant). (Column 16, lines 42-47).
- e. With respect to claim 36, TSEUNG teaches a method of staining tissue samples in an automatic staining apparatus comprising providing at least one removable reagent container (Column 5, lines 3-5); at least one slide (Column 5, lines 14-20); a robotic element adapted to affect said reagent container and said slide (Column 4, lines 10-14); a control element to which said robotic element is responsive (Column 5, lines 7-13); an optical sensor responsive to said robotic

Art Unit: 1797

element configured to two dimensionally image at least one element in said automatic staining apparatus (Column 16, lines 42-51); recording relevant image data and feeding the data to a control element to which the robotic element is responsive (Column 16, lines 42-47); wherein the control element monitors insertion or removal of the at least one slide and at least one removable reagent container during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1797

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2, 6-7, 17-19, 21-23, 25-30, and 32-34 are rejected under 35

U.S.C. 103(a) as being unpatentable over TSEUNG (US 5439649) in view of GANZ (WO 02/064812).

a. With respect to claim 2, TSEUNG does not explicitly disclose the optical sensor adapted to locate reference features to calibrate the robotic element. However, GANZ teaches an automated dispensing device to place reagents on slides in which a camera (optical sensor) images each slide and inspects (adapted to locate) the positioning and alignment of the slide (Page 5, Paragraph 5). Software in the control element analyzes this position data and uses it to adjust (self calibration) the positions of the slide and dispense head (robotic element) (Page 6, Paragraph 1). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the automatic tissue stainer of TSEUNG to include the camera adapted to calibrate the robotic element of GANZ because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1). TSEUNG and GANZ are analogous art because they are from the same field of endeavor of automated biological processing for analysis of slide samples.

b. With respect to claim 6, TSEUNG teaches the claimed invention (see rejection of claim 1), but does not explicitly disclose recording image data, robotic calibration points, and feeding the data to a control element. However, GANZ

teaches a camera that images the slides and software that analyzes the identification, positioning (robotic calibration reference points) and alignment information (relevant image data) provided by the camera and stores it (records) (Page 5, paragraph 5—Page 6, paragraph 1). GANZ teaches the camera sends the image information to software on a computer (control element) which uses the information to adjust the positions of the dispense head (responsive robotic element) (Page 6, paragraph 2). At the time of the invention it would have been obvious to modify the apparatus of TSEUNG to include the features of GANZ because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1).

c. With respect to claim 7, TSEUNG teaches the claimed invention (see rejection of claim 1) including providing slides in racks (Column 8, lines 9-14), but does not explicitly disclose the optical sensor responsive to the robotic element. However, GANZ teaches the camera (optical sensor) images the slide after the linear actuator (robotic element) moves the slide under the dispense head, therefore the optical sensor must respond to placement by the robotic element because this allows the camera to acquire position and alignment information of the slide (Page 6, paragraph 2). GANZ also teaches the camera images the slides and software analyzes the identification, positioning (robotic calibration reference points) and alignment information (relevant image data) provided by the camera and stores it (records) (Page 5, paragraph 5—Page 6, paragraph 1). GANZ teaches the camera sends the image information to software on a

computer (control element) which uses the information to adjust the positions of the dispense head (responsive robotic element) (Page 6, paragraph 2). At the time of the invention it would have been obvious to modify the method of TSEUNG to include the steps of GANZ because it ensures accurate placement of the reagent on the slide preventing inaccurate results (Page 6, paragraph 1). It would be an obvious modification of the device taught by GANZ to record calibration reference positions for the slide racks (holders) which contain the slides of TSEUNG as it doesn't require any additional technical features.

d. With respect to claim 17, TSEUNG teaches the claimed invention (see rejection of claim 1) except for a computer image biological analysis element and the optical sensor recording a first before image and a second after image. However GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2) and an optical sensor (camera) that records a first image of the sample before staining and records a second image of the sample after staining (Page 6, Paragraph 2 and Page 3, Paragraph 1). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the computer image analysis and two image recordings as taught by GANZ because before staining it allows for adjustment to the positions of the slides to ensure accurate placement of the reagent on the slide (Page 6,

Paragraph 2) and after it allows for determination of if the slides were properly stained (Page 10, Paragraph 2).

e. With respect to claims 18-19, GANZ teaches the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

f. With respect to claim 21, TSEUNG teaches the claimed invention (see rejection of claim 1) including the sample being placed on a slide in a removable slide rack (Column 5, lines 14-20) and wherein the control element monitors insertion or removal of the slide rack during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51), optically sensing a two dimensional image of at least one element in the apparatus (column 16, lines 42-47), recording relevant image data and feeding the data to a control element to which the robotic element is responsive (Column 16, lines 42-47), but does not explicitly disclose biologically analyzing image data of the sample with a computer. However GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the computer image analysis as taught by GANZ because it allows for determination of if the slides were properly stained (Page 10, Paragraph 2).

g. With respect to claims 22-23, GANZ teaches the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

h. With respect to claim 25, TSEUNG teaches a method of staining tissue sample in an automatic apparatus (see rejection of claim 1) including providing at least one removable sample (column 5, lines 14-20) wherein the control element monitors insertion or removal of the sample during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51), providing an optical sensor adapted to sense a two dimensional image of at least one element in the apparatus (column 16, lines 42-47), recording relevant image data and feeding the data to a control element to which the robotic element is responsive (Column 16, lines 42-47), but does not explicitly disclose biologically analyzing image data of the sample with a computer. However GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the computer image analysis as taught by GANZ because it allows for determination of if the slides were properly stained (Page 10, Paragraph 2).

i. With respect to claim 26, TSEUNG teaches providing one sample comprising the step of utilizing a slide (column 5, lines 14-20).

Art Unit: 1797

- j. With respect to claims 27-28, GANZ teaches providing the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).
- k. With respect to claim 29, GANZ teaches the step of storing an image relevant to a process of staining tissue samples (Page 6, Paragraph 2).
- l. With respect to claim 30, TSEUNG teaches the claimed apparatus (see rejection of claim 1) but does not explicitly disclose a multifunction optical sensor or computer image biological analysis element. However GANZ teaches a staining apparatus with a camera with a control computer that has software to inspect the stored camera images after reagent deposition onto a slide containing a biological sample (Page 10, Paragraph 2) and a multifunction optical sensor (read barcodes and inspect the positioning and alignment of a slide) configured to sense at least one element in said automatic staining apparatus (Page 6, Paragraph 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the computer image analysis as taught by GANZ because it allows for determination of if the slides were properly stained (Page 10, Paragraph 2) and having one optical sensor to complete multiple functions would save on space and manufacturing costs. The combined device of TSEUNG and GANZ would be capable of automatically identifying insertion of new slides and reagent containers into the staining apparatus as these are the functions of the optical

sensor of TSEUNG which reads barcodes and would be capable of being preformed by the multifunctional sensor of GANZ as it also reads barcodes.

m. With respect to claim 32-33, GANZ teaches the optical sensor comprises a camera which inherently comprises a CCD element (DVT Corporation series 600 model) (Page 14, Paragraph 2).

n. With respect to claim 34, GANZ teaches a stored image relevant to a process of staining tissue samples (Page 6, Paragraph 2).

11. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSEUNG (US 5439649) in view of RHETT (US 5839091).

a. With respect to claim 3, TSEUNG does explicitly disclose the optical sensor adapted to record an image of the finalized slide. However, RHETT teaches an apparatus for automatic slide staining in which the optical sensor (CCD camera) is adapted to record an image of the finalized slide after said slide has been subjected to a staining protocol (Column 14, lines 5-8). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the optical sensor recording an imaged of the finalized slide because it allows for the recalling of a complete history of each slide for analysis and diagnosis (Column 14, lines 5-9).

b. With respect to claim 4, TSEUNG teaches at least one element comprises an element consisting of a bar code (Column 16, lines 45-47) but does not explicitly disclose the optical sensor adapted to record an image of the finalized

Art Unit: 1797

slide. However, RHETT teaches an apparatus for automatic slide staining in which the optical sensor (CCD camera) is adapted to record an image of the finalized slide after said slide has been subjected to a staining protocol (Column 14, lines 5-8). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the optical sensor recording an image of the finalized slide because it allows for the recalling of a complete history of each slide for analysis and diagnosis (Column 14, lines 5-9).

c. With respect to claim 5, TSEUNG teaches the optical sensor is configured to identify a feature consisting of an individual identification feature of the slide (Column 16, lines 42-47) but does not explicitly disclose the optical sensor adapted to record an image of the finalized slide. However, RHETT teaches an apparatus for automatic slide staining in which the optical sensor (CCD camera) is adapted to record an image of the finalized slide after said slide has been subjected to a staining protocol (Column 14, lines 5-8). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the apparatus of TSEUNG to include the optical sensor recording an image of the finalized slide because it allows for the recalling of a complete history of each slide for analysis and diagnosis (Column 14, lines 5-9).

12. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSEUNG (US 5439649).

a. With respect to claims 14-15, TSEUNG teaches slide identification information (optical identification) in the form of a barcodes (Column 16, lines 42-47). It would have been obvious to one having ordinary skill in the art to use two dimensional high resolution symbology or data matrix codes in the optical identification art and selection of any of these known equivalents to use as slide identification in place of a barcode would be within the level of ordinary skill in the art (MPEP 2144.06).

13. Claims 9 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over TSEUNG (US 5439649) in view of BERNSTEIN (US 5696887).

a. With respect to claim 9, TSEUNG teaches an automatic staining apparatus comprising at least one reagent container positioned within a reagent section (Column 5, lines 3-5); at least one sample placed on a slide in a slide section (Column 5, lines 14-20); a robotic element adapted to affect said reagent container and said samples (Column 4, lines 10-14); a control element to which said robotic element is responsive (Column 5, lines 7-13), but does not explicitly disclose a first and second slide section separated by the reagent section. However, BERNSTEIN teaches an apparatus for automated tissue assay in which samples are located in two sections which are separated by an element (Figure 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of TSEUNG to include the arrangement of slides as taught by BERNSTEIN because it allows for the robotic

Art Unit: 1797

device to have sufficient degrees of freedom to reach each slide and processing station with suitable movement (Column 4, lines 30-41).

b. With respect to claim 35, TSEUNG teaches an automatic staining apparatus comprising at least one removable reagent container positioned within a reagent section (Column 5, lines 3-5); at least one sample placed on a slide in a slide rack (Column 5, lines 14-20); a robotic element adapted to affect said reagent container and said sample (Column 4, lines 10-14); a control element to which said robotic element is responsive (Column 5, lines 7-13); an image capture 2D optical sensor configured to two dimensionally image at least one element in said automatic staining apparatus (Column 16, lines 42-51); wherein the control element monitors insertion or removal of the at least one slide rack during processing protocol steps (Column 4, lines 10-14 and Column 16, lines 42-51) but does not explicitly disclose two staining sections separated by the reagent section. However, BERNSTEIN teaches an apparatus for automated tissue assay in which samples are located in two sections which are separated by an element (Figure 2). At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of TSEUNG to include the arrangement of slides as taught by BERNSTEIN because it allows for the robotic device to have sufficient degrees of freedom to reach each slide and processing station with suitable movement (Column 4, lines 30-41).

Response to Arguments

14. Applicant's arguments with respect to claims 1-5, 7-19, 21-23, 25-30, and 32-34 have been considered but are moot in view of the new ground(s) of rejection.

15. In response to Applicant's argument regarding claim 6, on pages 23-24 that GANZ teaches recording reference points of the slide and not the apparatus, the Examiner maintains that recording reference points of the slide is recording reference points of the apparatus as the claims specify the apparatus comprises the slide (See Claims 1 and 6).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 11am-8pm, Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DANIELLE HENKEL/

Examiner, Art Unit 1797

Supervisory Patent Examiner, Art Unit 1797

/Jill Warden/

Supervisory Patent Examiner, Art Unit 1797